Model 5392

Dual Chamber Temporary Pacemaker Checkout Manual

Table of Contents

PAGE

Purpose and Scope of This Document . . . 1
Returning a Temporary Pacemaker to Medtronic . . . 2
5392 Control Description . . . 2
Test Parameter Definitions . . . 3
Test Conditions . . . 4
Test Equipment . . . 4
Test Procedures . . . 5
- 1) Rate . . . 5
- 2) Rapid Atrial Pacing Test (RAP) . . . 5
- 3) Output . . . 6
- 4) Pulse Width . . . 7
- 5) A/V Interval . . . 8
- 6) Sensitivity . . . 8
- 7) Emergency . . . 9
- 8) Inactive Current Drain . . . 9
- 9) Active Current Drain . . . 10
- 10) Battery Removal – Pacing Continuation Test . . . 10

Error Buttons and Messages . . . 11
5392 Service Life Statement . . . 11
Returned Product Information Report . . . 12

Purpose and Scope of This Document

This manual is intended for use by a qualified engineer or technician for the purpose of checking the operation of a Medtronic Model 5392 Dual Chamber Temporary Pacemaker. The instructions in this manual cover testing the electrical parameters of the Model 5392 temporary pacemaker. If checkout of a temporary pacemaker indicates improper operation, the unit should be returned to Medtronic for evaluation and repair.

Medtronic does not recommend field repair of this device. Refer to terms of the limited warranty covered in the Model 5392 Dual Chamber Temporary Pacemaker Technical Manual supplied with the device.

Note: There is no method to adjust an out-of-tolerance parameter at an off-site location. The device must be returned for recalibration.

Refer to the Model 5392 Dual Chamber Temporary Pacemaker Technical Manual for a complete description, operating instructions, cleaning and maintenance instructions, and specifications for this device.

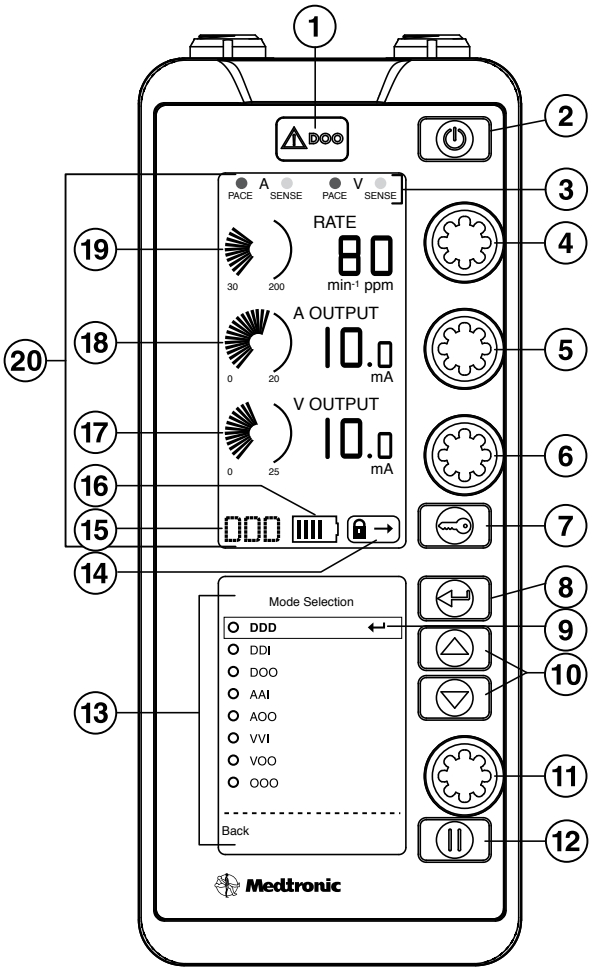
Returning a Temporary Pacemaker to Medtronic

To return a damaged or malfunctioning Model 5392 Dual Chamber Temporary Pacemaker to Medtronic for evaluation and repair, fill out the information requested on the Returned Product Information Report at the back of this manual. Send this information and the temporary pacemaker to:

Medtronic, Inc.
7000 Central Avenue, NE
Dock B
Minneapolis, MN 55432-3576

Attention: Instrument Service Department

For questions please call 1 (800) 638-1991 and ask for Instrument Technical Services or email epghelp@medtronic.com.



1 DOO/Emergency key
2 On/Off key
3 Pacing and sensing status bar indicators
4 Rate dial
5 A (Atrial) Output dial
6 V (Ventricular) Output dial
7 Lock/Unlock key
8 Enter key
9 Selection indicator
10 Up/Down arrow keys
11 Menu Parameter dial
12 Pause key
13 Lower screen
14 Lock indicator
15 Pacing Mode indicator
16 Battery indicator
17 V (Ventricular) Output scale
18 A (Atrial) Output scale
19 Rate scale
20 Upper screen

Figure 1. The Model 5392 Temporary Pacemaker

Test Parameter Definitions

The following paragraphs define each of the test parameters covered by the checkout procedures in this manual.

1) **Rate** – Rate is the number of output pulses per minute (ppm). It is the inverse of the time interval between output pulses, measured from leading edge to leading edge at the half-peak amplitude points. The rate control knob sets the atrial and the ventricular rates. Pulse rate is measured as average rate over more than 1 pulse.

2) **Rapid Atrial Pacing Rate** – High rate is delivered only to the atrium and is measured in the same manner as the rate.

3) **Pulse Width** – Pulse width is the time interval in milliseconds (ms) between the leading and trailing edges of the output pulse measured at the half-peak amplitude points. In this pacemaker, the Atrial Pulse Width is fixed at 1.0 ms and the Ventricular Pulse Width is fixed at 1.5 ms. Pulse widths are measured at 33% of peak amplitude.

4) **AV Interval** – AV interval is the interval between the atrial and ventricular output pulses. It is measured from leading edge of the atrial output to leading edge of the ventricular output at the half-peak amplitude points.

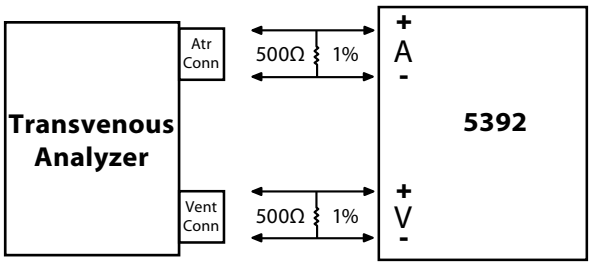
5) **Output** – Output is in milliamps (mA) and is equal to the amplitude of the output pulse in volts, measured at the mid-width point, divided by the load resistance in ohms (500 ohms is the nominal load resistance).

6) **Direct Current Leakage** – When the device is on, this test measures the DC leakage current in the time interval between output pulses.

7) **Sensitivity** – This parameter represents the signal level that the amplitude of an intrinsic atrial or ventricular depolarization signal must exceed to be detected as a sensed event. Sensitivity is tested by determining the amplitude of sine-squared pulses (simulated P- or R- waves) that will inhibit pacing. This test first injects a sub-threshold signal (the device paces), then the amplitude is slowly increased until it is above threshold (the device senses). Valid Sensing occurs when the DUT detects 5 out of 5 inputs. Valid No Sense when the DUT detects 0 out of 5 inputs.

8) **Emergency** – The test verifies maximum atrial and ventricular output in mA at the current Rate setting, when the Emergency key is depressed. If the 5392 is in an "off" state, pressing the Emergency key will automatically turn the device "on."

9) **Operation after Battery Removal** – Medtronic does not recommend replacing the batteries while the pacemaker is turned on or actively pacing the patient. The 5392 will operate after battery removal for a minimum 30 s (typical) under the following conditions: RATE of 80 ppm or less, A OUTPUT and V OUTPUT of 10 mA or less, backlight off, and lower screen blank.



Test Function	Analyzer
Rate Output Pulse Width A/V Interval Sensitivity	Transvenous Pacemaker Analyzer
DC Current Leakage	DC millivolt meter/analyzer

Figure 2. Setup for Testing 5392
Note: Transvenous analyzers have a built-in 500 ohm load on the inputs

Test Conditions

For accurate measurement of device parameters, test instrument inaccuracy should not exceed 10 percent of the tolerance for that particular parameter. An oscilloscope may be used, but due to instrument tolerances, measured values should be considered relative rather than exact.

Measurements are to be made under the following conditions and at the specified parameter settings.

- All unspecified tolerances ± 5%
- Temperature 70 ± 10 °F
- Relative humidity 80% or less
- Normal output load 500 ohms ± 1%
- Battery voltage 3.0 ± 0.5% DC (1.5 ± 5% per AA cell)
- Battery type Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent)
- Simulated P-wave 20 ms, $sine^2$ pulse at 400 ms intervals
- Simulated R-wave 40 ms, $sine^2$ pulse at 400 ms
- Device settings shall be the default settings in the DDD mode, unless otherwise specified:

MODE	DDD
LOWER RATE	80 ppm
UPPER RATE	110 ppm (base rate + 30 ppm)
A OUTPUT	10.0 mA
V OUTPUT	10.0 mA
A SENSITIVITY	0.4 mV
V SENSITIVITY	2.0 mV
A PULSE WIDTH	1.0 ms
V PULSE WIDTH	1.5 ms
AV INTERVAL	170 ms

Test Equipment

Medtronic recommends only the use of a transvenous external pacemaker analyzer for testing the Model 5392.

For all tests use a 500 ohm load. The external transvenous pacemaker analyzer may require the selection of type which is "invasive."

Test Procedures

GENERAL

To change a parameter value, adjust the appropriate control knob for the required parameter value while observing the LCD numeric value displayed.

The pacing load for this device consists of a 500 ohm, ± 1% resistor, in parallel or installed across the atrial and/or ventricular outputs.

1) Rate

a) Test Setup
Connect the temporary pacemaker to a transvenous external pacemaker analyzer; select "Invasive" (if required) and 500 ohms for the load, and then proceed to test.

b) On the 5392 change the mode to AAI by setting the V OUTPUT to 0 mA (OFF). Adjust the A OUTPUT to 10 mA. Set the Atrial Rate to the values listed below, and verify that the measured atrial pulse intervals are within specified tolerances.

Rate Setting	Specified Tolerance	Pulse Range
30 ppm	± 2%	29 – 31 ppm
80 ppm	± 2%	78 – 82 ppm
120 ppm	± 2%	117 – 123 ppm
200 ppm	± 2%	196 – 204 ppm

c) On the 5392 change the mode to VVI by setting the A OUTPUT to 0 mA (OFF). Adjust the V OUTPUT to 10 mA. Set Ventricular Rate to the values listed above, and verify that the measured ventricular pulse rates are within specified tolerance.

2) Rapid Atrial Pacing Test (RAP)

a) Test Setup
Connect the temporary EPG to a transvenous external pacemaker analyzer. The RAP test is performed using the Rate test on the analyzer.

b) Select the RAP mode from 5392 Lower Screen. Set the RAP rate to 800 ppm with the "Menu Parameter Dial." To deliver RAP, depress and hold the "ENTER" key. The A Pace LED will flash at the RAP rate. The V Pace LED will stop flashing, indicating no V Pace. Verify on the analyzer that the atrial rate is 800 ppm ± 4% (768 – 832 ppm). Release the "ENTER" key to discontinue RAP.

RAP Setting	Specified Tolerance	RAP Range
180 ppm	± 2%	176 – 184 ppm
250 ppm	± 2%	245 – 255 ppm
360 ppm	± 2%	353 – 367 ppm
800 ppm	± 2%	784 – 816 ppm

3) Output

a) Setup

Connect the temporary pacemaker to a transvenous pacemaker analyzer. Set the mode to VVI mode by turning the A OUTPUT to 0 mA (OFF). Adjust the V OUTPUT to 10 mA. Select from the test analyzer the "Pulse Output" or "Output" test. This output test is measuring the ventricular output amplitude at the 50% point of the output pulse and dividing this value by the load resistance (500 ohms) to get the value for output current which will verify that the measured outputs are within specified limits.

Ventricular Current Output Specifications

Output	Tolerance	Range mA
1.0 mA	± 10%	0.9 – 1.1 mA
5.0 mA	± 10%	4.5 – 5.5 mA
10.0 mA	± 10%	9.0 – 11 mA
25.0 mA	± 10%	22.5 – 27.5 mA

b) Setup

Connect the temporary pacemaker to a transvenous pacemaker analyzer. Set the mode to AAI mode by turning the V OUTPUT to 0 mA (OFF). Adjust the A OUTPUT to 10 mA. Select from the test analyzer the "Pulse Output" or "Output" test. This output test is measuring the atrial output amplitude at the 50% point of the output pulse and dividing this value by the load resistance (500 ohms) to get the value for output current which will verify that the measured outputs are within specified limits.

Atrial Current Output Specifications

Output	Tolerance	Range mA
1.0 mA	± 10%	0.9 – 1.1 mA
5.0 mA	± 10%	4.5 – 5.5 mA
10.0 mA	± 10%	9.0 – 11.0 mA
20.0 mA	± 10%	18.0 – 22.0 mA

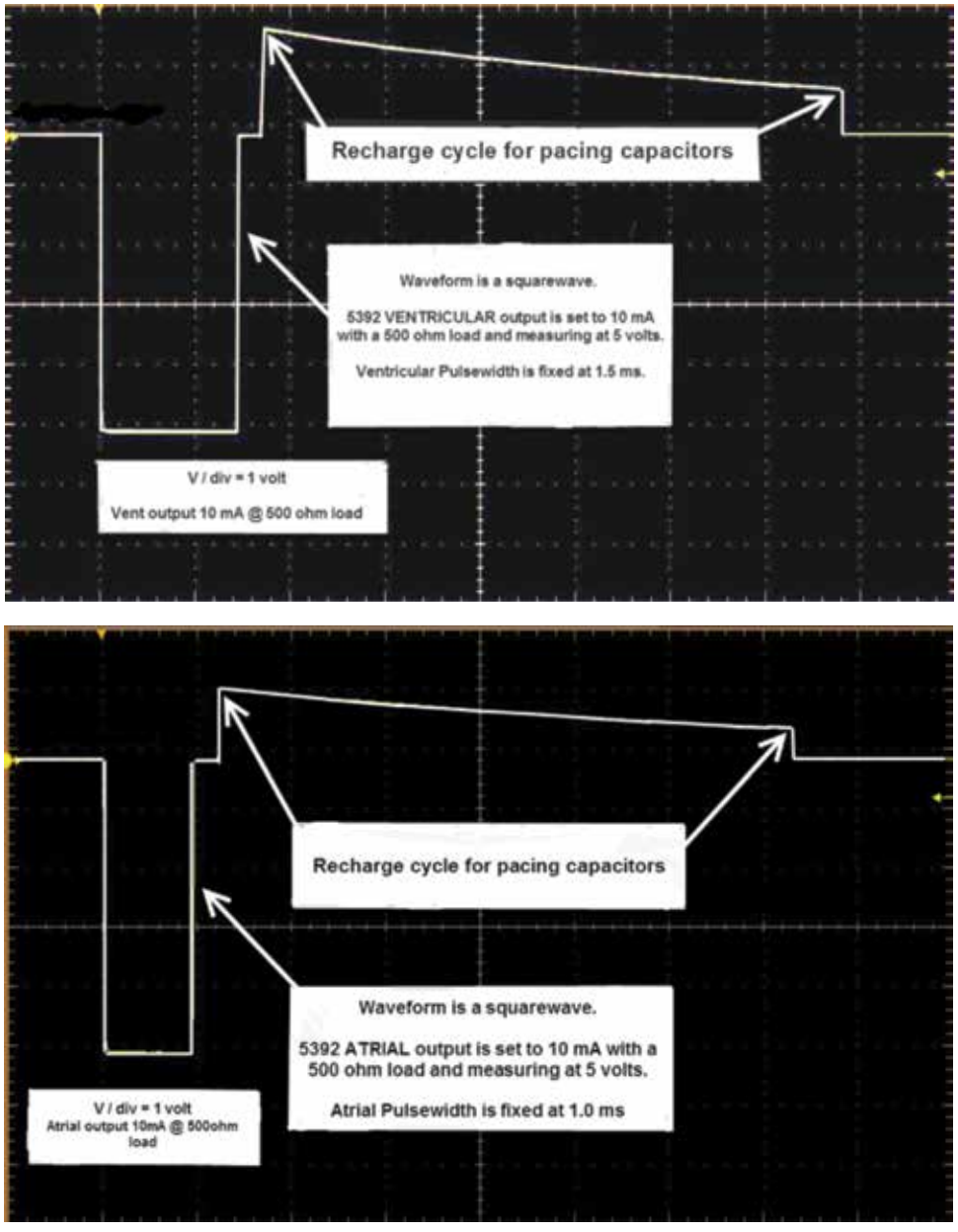

Recharge cycle for pacing capacitors
Waveform is a squarewave.
5392 VENTRICULAR output is set to 10 mA with a 500 ohm load and measuring at 5 volts.
Ventricular Pulsewidth is fixed at 1.5 ms.
V / div = 1 volt
Vent output 10 mA @ 500 ohm load
Recharge cycle for pacing capacitors
Waveform is a squarewave.
5392 ATRIAL output is set to 10 mA with a 500 ohm load and measuring at 5 volts.
Atrial Pulsewidth is fixed at 1.0 ms
V / div = 1 volt
Atrial output 10mA @ 500ohm load

Figure 3: Top – Ventricular Waveform, Bottom – Atrial Waveform

4) Pulse Width

a) Test Setup

Connect the temporary pacemaker to a transvenous external pacemaker analyzer using a 500 ± 1% ohm load across each output, per figure 2. Using the Pulse Width Test function of analyzer to measure the period of time between the leading edge of the pulse to the negative edge of the pulse measured at 33% peak amplitude.

b) Set the mode to AAI by turning the V OUTPUT to 0 mA (OFF). Adjust the A OUTPUT to 10 mA. Connect the analyzer test leads to the atrial output. The Atrial Pulse Width is fixed at 1.0 ms ± 10% (0.90 - 1.10 ms). Verify the Atrial Pulse Width on the transvenous external pacemaker analyzer.

c) Change the mode to VVI mode by setting the A OUTPUT to 0 mA (OFF). Adjust the V OUTPUT to 10 mA. Connect the analyzer test leads to the ventricular output. The Ventricular Pulse Width is fixed at 1.5 ms ± 10% (1.35 - 1.65 ms). Verify the Ventricular Pulse Width on the transvenous external pacemaker analyzer.

5) A/V Interval

a) Test Setup

With the temporary pacemaker in the DDD mode, connect the temporary pacemaker according to the setup shown in Figure 2.

Option A) Using a transvenous analyzer, select the "Pulse Interval" test, using a 500 ohm load. Use the default settings of the 5392 for testing. On the lower screen select A – V Interval by pressing the DOWN arrow until A – V Interval is selected. Increase or decrease the A – V Interval by turning "Menu Parameter Dial" (refer to page 3).

Test per settings below in b.

Option B) Using a scope, trigger on the leading edge of the pulse for channel A (connected to the atrial output), and on the leading edge of channel B, pulse (connected to the ventricular output) at the half-peak (pulse) points. Measure the time interval between an atrial output pulse and the following ventricular output pulse. Alternatively, a scope may be used by setting the sensitivities to ASYNC and parallel the outputs across a single 500 ohm resistor load. Adjust the time base of the scope to observe the interval between the leading edge of the atrial pulse to the leading edge of the ventricular pulse.

b) Set the device to the following AV intervals and verify that the readings meet the specifications.

Rate	AV Interval	Spec.	Range
30 ppm	250 ms	± 5%	237.5 – 262.5 ms
80 ppm	170 ms	± 5%	161.5 – 178.5 ms
120 ppm	100 ms	± 5%	95.0 – 105.0 ms
200 ppm	50 ms	± 5%	47.5 – 52.5 ms

6) Sensitivity

a) Test Setup

Connect the device according to the test setup shown in Figure 2. Connect the 5392 to a transvenous pacemaker analyzer. Select "Sense Amp" or "Sensitivity" and then select atrial or ventricular test.

- For measuring atrial sensitivity, use a simulated P-wave input (20 ms $sine^2$ pulse at 400 ms intervals)
- For measuring ventricular sensitivity, use a simulated R-wave input (40 ms $sine^2$ pulse at 400 ms intervals)

Atrial Sensitivity

Set the sensitivity control, via Lower Display of 5392, to the values listed in the table, below. For measuring atrial sensitivity, set the device to AAI mode by setting the Ventricular output to 0 mA (OFF). At each test setting, increase the output (simulated P wave or R wave) of the analyzer, either manually or automatically, from below sensing threshold (device paces) to above threshold (device senses a minimum of five consecutive input signals). The sensing threshold must fall within the range specified for each setting.

Sensitivity Atrial	Tolerance	Threshold
1.0 mV	± 60%	0.4 – 1.6 mV
2.0 mV	± 40%	1.20 – 2.80 mV
5.0 mV	± 40%	3.00 – 7.0 mV
10.0 mV	± 40%	6.0 – 14.0 mV

Ventricular Sensitivity

Set the sensitivity control, via Lower Display of the 5392, to the values listed in the table, below. For measuring ventricular sensitivity, set the device to VVI mode by setting the Atrial output to 0 mA (OFF). At each test setting, increase the output (simulated P wave or R wave) of the analyzer, either manually or automatically, from below sensing threshold (device paces) to above threshold (device senses a minimum of five consecutive input signals). The sensing threshold must fall within the range specified for each setting.

Sensitivity Ventricular	Tolerance	Threshold
1.0 mV	± 55%	0.45 – 1.55 mV
3.0 mV	± 55%	1.35 – 4.65 mV
10.0 mV	± 55%	4.50 – 15.50 mV
20.0 mV	± 55%	9.0 – 31.0 mV

7) Emergency (Optional)

a) Test Setup
Set the temporary pacemaker to the DDD mode. The test is conducted using the setup in Figure 2. Connect the 5392 to a transvenous analyzer. Depress the DOO key. Refer to Figure 1.

b) Using the analyzer, measure the Atrial Output and verify output current as 20 mA ± 10% (18 - 22 mA).

c) Using the analyzer, measure the Ventricular Output and verify the output current as 25 mA ± 10% (22.5 - 27.5 mA).

Note: When the DOO/Emergency key is pressed, the current rate setting (or 80 ppm if the temporary pacemaker was off before the DOO/Emergency key was pressed), will be measured through the analyzer.

8) Inactive Current Drain (Optional)

a) Test Setup
Connect the temporary pacemaker according to the setup shown in Figure 2 with the monitor being a DC voltmeter, micro amp meter or transvenous analyzer, (determine if this function is available with the analyzer).

b) With the 5392 turned "OFF," measure the DC voltage across the 500 ohm atrial load resistor, then across the 500 ohm ventricular load resistor. Verify that the value is as specified below.

Note: The 5392 must be in an "OFF" state a minimum of 1 minute before measurement. If it can be determined that the device has been powered on for at least 1 minute during previous tests, proceed to the next step. If the 5392 has been turned "OFF" for this test, wait a minimum of 1 minute before proceeding.

Specification	≥ 0 and ≤ 10 µA

9) Active Current Drain (Optional)

Connect the temporary pacemaker according to the setup shown in Figure 2 with the monitor being a DC voltmeter, micro amp meter or transvenous analyzer, (determine if this function is available with the analyzer).

Backlight OFF

a) Turn the 5392 "ON "and wait a minimum 1 minute to allow the pacing capacitors to fully charge. Verify default settings: rate = 80 bpm, Atrial Output = 10 mA, Ventricular Output = 10 mA.
b) Turn the Backlight and Menu screen OFF by pressing the "Lock" key.
c) Verify that the DC current drawn by the 5392 is > 9 mA and < 18 mA.

Backlight and Menu ON

a) Turn the 5392 "ON" and verify default settings of: rate = 80 bpm, Atrial Output = 10 mA, Ventricular Output = 10 mA.
b) Turn the Backlight and Menu ON by pressing the "Lock" key.
c) Verify that the DC current drawn by the 5392 is > 13 mA and < 24 mA.

Low Voltage

a) Turn the Backlight and Menu OFF by pressing the "Lock" key.
b) The 5392 will need 2 AA batteries with a total voltage of 2.0 + 5%, or will need to be connected to a DC power supply.
c) Set the voltage to 2.0 + 5% VDC, on the DC power supply.
d) Verify that the DC current drawn by the 5392 is >13.5 mA and <27 mA.

10) Battery Removal – Pacing Continuation Test (Optional)

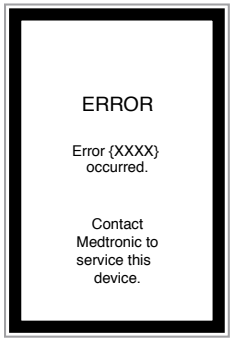
Pacing Continuation Test

a) Connect the 5392 to a transvenous test analyzer, using the output test function to complete this test. Or connect the 5392 to an oscilloscope for measuring and monitoring the Output.
b) Verify the battery voltage is 3.0 + .5 VDC.
c) Turn the 5392 "ON" and verify default settings of rate = 80 bpm, Atrial Output = 10 mA, Ventricular Output = 10 mA. (Wait a minimum of 1 minute to allow pacing capacitors to fully charge).
d) Turn the Backlight and Lower Display OFF by pressing the "Lock" key.
e) If it can be determined that the device has been powered on for at least 30 seconds during previous tests, wait a minimum of 1 minute, then proceed to the next step.
Or, wait for a minimum 1 minute (to allow for the capacitors to charge, if running tests out of order).
f) Disconnect power from the 5392.
g) Verify that the Atrial and Ventricular output amplitude is 10 mA + 10% after 30 seconds.

Error Messages

TYPES OF ERROR MESSAGES
Note the ERROR Message and contact Medtronic Instrument Technical Services. Refer to page 2 for contact information.

Recoverable Error Message	Button Press Detected Error Message	Non-Recoverable Error Message
If the temporary pacemaker displays the Recoverable error message (below) in the lower screen, press the Enter key. The temporary pacemaker restarts and performs the self-test.	If the temporary pacemaker displays the Button Press Detected error message in the lower screen, a button has been pressed while the temporary pacemaker is turning on. Release any pressed key and the temporary pacemaker continues to power on normally.	If the temporary pacemaker displays the Non-Recoverable error message (see below) in the lower screen, contact Medtronic Instrument Technical Services.



5392 Service Life

Medtronic will no longer service or calibrate EPGs that are more than 5 years old, based on date of sale. EPGs that are equal to or less than 5 years old can be serviced and calibrated.

Medtronic recommends that the 5392 have the calibration verified at minimum once every 12 months. When the 5392 reaches end of Medtronic Service Life, the 5392 can continue to be used, based on the physical condition and continued scheduled preventive maintenance checks (refer to the 5392 Technical Manual). The scheduled preventive maintenance checks would have to be completed using a transvenous temporary pacemaker analyzer. The testing would verify the functions as stated within the 5392 Checkout Manual and the test results to be found within the stated tolerances of 5392 Checkout Manual. Contact Medtronic Instrument Technical Services, 1 (800) 638-1991 with questions regarding testing and functionality.

www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)

UC201402092 EN © Medtronic, Inc. 2014. Minneapolis, MN. All Rights Reserved. Printed in USA. 10/2014